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10/627,739	07/28/2003	**Gila Maor**	26243	4122

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EXAMINER	
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ART UNIT	PAPER NUMBER
1651	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/627,739	MAOR, GILA	
	Examiner	Art Unit	
	Lora E. Barnhart	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 October 2007 and 15 May 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-9,11-106 and 108* is/are pending in the application.

4a) Of the above claim(s) *12,13,15,16 and 24-103* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9,11,14,17-23,104-106 and 108* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *19 October 2007* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendments

Applicant's amendments filed 10/19/07 to claims 1, 2, 6, 21-23, and 104 have been entered. Claim 107 has been cancelled in this reply. Claim 108 has been added. Claims 1-9, 11-106, and 108 remain pending in the current application, of which claims 1-9, 11, 14, 17-23, 104-106, and 108 are being considered on their merits. Claims 12, 13, 15, 16, and 24-103 remain withdrawn from consideration at this time. Prior art references not included with this Office action can be found in a prior action.

It is noted that claims 12, 13, 15, and 16 have been provided with the status identifier "original," but these claims are withdrawn. Failure to provide all claims with correct status identifiers in the future will result in a notice of noncompliance with 37 C.F.R. 1.121(c).

Election/Restrictions

Applicant's election on 3/15/07 of the species "IGF" (as in claims 14 and 17) is still in effect over the claims.

Drawings

The objection to the drawings is withdrawn in light of applicants' submission of a petition under 37 C.F.R. 1.84(a)(2), the necessary copies of color drawings, and the amendment to the specification. A decision on the petition will be mailed by SPE Wityshyn in a separate letter.

Specification

The objection to the specification is withdrawn in light of the submission of the compliant replacement abstract on 5/15/08.

Claim Rejections - 35 USC § 112

Any rejections of record under 35 U.S.C. § 112 not particularly addressed below are withdrawn in light of the claim amendments.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-9, 11, 14, 17-23, and 108 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of generating cultured chondrocytes that express type II collagen but not type I collagen by using one particular set of culture conditions, does not reasonably provide enablement for doing so using any given medium and culture conditions. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The factors to be considered in determining whether undue experimentation is required are summarized in *In re Wands*, 858 F.2d 731, 737, 8 USPQd 1400, 1404 (Fed. Cir. 1988) (a) the breadth of the claims; (b) the nature of the invention; (c) the state of the prior art; (d) the level of one of ordinary skill; (e) the level of predictability in the art; (f) the amount of direction provided by the inventor; (g) the existence of working examples; and (h) the quantity of experimentation needed to make or use the invention

based on the content of the disclosure. While all of these factors are considered, a sufficient number are discussed below so as to create a *prima facie* case.

Claim 1 is broadly drawn to a method in which chondrocytes along with other cells are isolated from mandibular condyle tissue, then cultured under some undisclosed conditions to yield chondrocytes that express type II, but not type I, collagen. Claim 2 requires that the isolation step comprise some sort of selective process in which some non-chondrocyte cell types are removed from the tissue and another selective process in which chondrocytes are isolated from the tissue. Claims 3-5 discuss the manner in which the condyle tissue is dissociated. Claims 6-9, 11, and 17-22 describe the culturing conditions; it is noted that claims 6-9, 11, and 17 describe the culture conditions in terms of what they do not include, rather than what they do include. Claims 23 and 108 describe the source of the chondrocytes.

Schnabel et al. (2002, *Osteoarthritis and Cartilage* 10: 62-70; reference U) teach that chondrocytes isolated from cartilage and cultured in monolayers using standard tissue culture techniques tend to dedifferentiate to a fibroblast-like state over time (page 62, column 2). Specifically, freshly isolated chondrocytes produce primarily type II collagen, but after a few weeks in monolayer culture, chondrocytes shift their expression pattern to the production of type I collagen (page 63, column 2, last paragraph; and page 67)[1]. Schnabel indicates that the loss of type II collagen expression is a long-standing problem in the cartilage replacement art (pages 67 and 69).

[1] It is noted that applicant's comments discuss this phenomenon (Reply, page 22, paragraph 1, e.g.) and refer to various non-patent publications in support of the position, but no copies of these publications were furnished with the reply, so they could not be fully considered.

Efforts have been made in the art to preserve the expression of collagen II in cultured chondrocytes. Cheung (1988, U.S. Patent 4,757,017; reference A) teaches a system in which articular chondrocytes are cultured on particles of hydroxyapatite in serum-supplemented media; in the system of Cheung, cultured chondrocytes retain their expression of type II collagen for extended periods of time (Example 1 at column 5 et seq., especially column 9, lines 4-24; and column 3, lines 4-11). However, Cheung teaches that culturing on hydroxyapatite is essential to preventing dedifferentiation of the chondrocytes (column 9, lines 4-24). Given the teachings of the art, at the time of the invention, the skilled artisan would have reasonably expected that chondrocytes cultured in monolayers *in vitro* will eventually exchange expression of collagen II for that of collagen I.

The as-filed specification includes working examples in which mandibular condyles from neonatal mice are harvested and subjected to several rounds of enzymatic treatment: a first to free non-chondrocytes from the tissue, which are removed, and additional treatments to digest the remaining cartilage, yielding chondrocytes (page 43, line 29, through page 44, line 15). The resulting chondrocytes are cultured in DMEM supplemented with serum and ascorbic acid, β-glycerophosphate, calcium chloride, and pyruvate (hereafter "chondrocyte culturing medium"; page 44, lines 15-23). The specification indicates that after three days in chondrocyte culturing medium, the chondrocytes began to dedifferentiate, as marked by their production of type I collagen, but after 7 days, they appeared to redifferentiate to functional chondrocytes producing type II collagen (page 48, lines 5-29).

The scope of the single pertinent working example is insufficient to support the instant claims. Schnabel and Cheung teach that generally, chondrocytes cultured without a scaffold (e.g. the hydroxyapatite of Cheung) dedifferentiate irreversibly in culture. Applicants have identified one culture media (the chondrocyte culturing medium) that may be used to produce type II collagen-producing chondrocytes after at least 7 days in culture. The instant claims do not materially limit the components of the culture media used for the method, because as discussed above, they primarily indicate what is **not** present in the media. There are no requirements that the cells be cultured for at least 7 days (i.e., beyond the "short dedifferentiation phase"; page 48, line 27) in order to yield the desired product; indeed, claim 20 allows that the culturing may be less than 7 days long, and there is no evidence on the record that at 5 days, the method described in the working examples would yield type II-producing chondrocytes. It is noted that claims 6-9 require that the cells be grown in a monolayer, but none of these claims places any limitations on the contents of the media or the length of the culturing.

The working example indicates that both the components of the media and the time for which the cells are cultured are essential elements of the invention, given the teachings in the art that merely culturing chondrocytes in a monolayer (which is the scope of claim 6) would not yield type II collagen-producing chondrocytes. While a singular, narrow working embodiment cannot be a sole factor in determining enablement, its limited showing, in light of the unpredictable nature of the art as to identifying conditions in which chondrocytes can grow in monolayer culture and retain their expression of type II collagen and the lack of direction applicants present for all

embodiments of the claims, provides additional weight to the lack of enablement in consideration of the *Wands* factors as a whole. Thus, one of ordinary skill in the art would not have a reasonable expectation of success in using the claimed invention across its entire scope.

Claims 6-9 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Claim 6 depends from claim 1 and requires that step (b) of claim 1, which necessarily yields cultured chondrocytes that express type II collagen but not type I collagen, be carried out using conditions devoid of a three-dimensional support such that the chondrocytes form a monolayer. Claims 7-9 depend from claim 6.

There is no support, either implicit or explicit, for the requirement that the culturing step of claim 1 yield a monolayer of cultured chondrocytes that express type II collagen but not type I collagen. Applicant stipulates in the remarks that a three-dimensional support "allows cells to grow in more than one layer" (page 20, paragraph 2 under letter "C"), and claim 6 precludes such a support being present. However, the as-filed specification does not indicate that the instant method includes true monolayer culturing of chondrocytes that express type II collagen but not type I collagen. Lines 19-23 at page 44 discuss a procedure in which chondrocytes are cultured, likely in a

monolayer, and after 2-3 weeks develop "cartilaginous nodules." Page 48, lines 5-29, indicate that for the first week of culture, the chondrocytes express type I collagen, but after a few weeks form "nodular cells" or "cartilage-forming nodules" that express type II collagen. Figures 3e and 3f, which show the culture at 7 and 14 days, respectively, appear to show multilayered clusters of cells; indeed, the word "nodule" refers to an aggregate or mass, which is by definition not single-layered. The specification appears to provide support for a method in which chondrocytes are plated in monolayer culture and, over time, form multi-layered aggregates that express type II collagen; the specification does not provide support for a method in which chondrocytes are cultured in true monolayers and express type II but not type I collagen.

Claim Rejections - 35 USC § 102

Any rejections of record under 35 U.S.C. § 102 not specifically discussed below are withdrawn in light of the amendments to the claims and/or applicant's comments.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 104-106 remain rejected under 35 U.S.C. 102(b) as being anticipated by Bhalerao et al. (1995, *Tissue and Cell* 27: 369-382).

Bhalerao teaches incubating mouse mandibular condyles in DMEM/F-12 containing 0.1% collagenase, a protease, and agitating the tissue to liberate cells into the medium (page 370, column 2, under "Preparation of cell suspension"). The

disaggregation procedure of Bhalerao is conducted in intervals, i.e. the tissue is digested for 30 minutes, after which time liberated cells are removed and the tissue is provided with fresh enzymatic solution. These steps are carried out a total of 3 times, after which a population of chondrocytes is isolated.

The discovery of a new use for an old structure based on unknown properties of the structure *might* be patentable to the discoverer as a process of using. *In re Hack*, 245 F.2d 246, 248, 114 USPQ 161, 163 (CCPA 1957). However, when the claim recites using an old composition or structure and the "use" is directed to a result or property of that composition or structure, then the claim is anticipated. *In re May*, 574 F.2d 1082, 1090, 197 USPQ 601, 607 (CCPA 1978) and *In re Tomlinson*, 363 F.2d 928, 150 USPQ 623 (CCPA 1966). See M.P.E.P. § 2112.02.

Bhalerao teach dissociation of mandibular condyles by repeated application of fresh collagenase solution and removal of cells after each application (page 370, column 2, paragraph 1). While Bhalerao does not teach that these steps selectively remove fibroblast-like cells and myocytes and yield an enriched population of chondrocytes, they do perform the same steps as in the present application (page 43, line 29, through page 44, line 8). Because the method steps (i.e. sequential digestion of mandibular condyles) are the same, Bhalerao inherently teach the same process of isolating chondrocytes as in the current application. Bhalerao therefore anticipates the selective isolation of chondrocytes as instantly claimed.

Applicant alleges that Bhalerao does not teach chondrocytes because they are genetically immortalized (Reply, page 21, last paragraph). Applicant alleges that the

cells of Bhalerao express type I collagen (Reply, page 22, paragraphs 1-2). Applicant alleges that Bhalerao teaches pooling all of the cells from their enzymatic digestions and therefore do not teach an enriched population of chondrocytes (Reply, page 22, last paragraph et seq.). These arguments have been fully considered, but they are not persuasive.

While Bhalerao does teach pooling the cells obtained from each step of their enzymatic digestion method and subsequently transforming them into immortalized lines, Bhalerao teaches the same steps as those described in the specification and therefore teaches the same outcome. Whether Bhalerao subjects their cells to subsequent downstream applications does not change the fact that the steps described at the first paragraph of page 370, column 2, yield several aliquots of cells each liberated by a single application of enzyme. The fact that Bhalerao specifically teaches that the cells were pooled indicates that the aliquots were collected individually and then added together; in other words, Bhalerao conducts the same steps as those carried out by applicant, yielding several different cell populations including one that is inherently an enriched population of chondrocytes, and then pools them, yielding a separate product. While Bhalerao's work has a different end point than that envisaged by applicant, Bhalerao's method does produce an enriched population of chondrocytes as an intermediate product and therefore anticipates the claimed method.

Regarding the expression of collagen, claims 104-106 do not require that any collagens be expressed or not expressed. These arguments are not pertinent to the cited claims.

Claim Rejections - 35 USC § 103

Any rejections of record under 35 U.S.C. § 103 not specifically discussed below are withdrawn in light of the amendments to the claims and/or applicant's comments.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-5, 11, 14, 17-21, 23, and 108 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cheung (1988, U.S. Patent 4,757,017; reference A) taken in view of Bhalerao (1995, *Tissue and Cell* 27: 369-382).

Cheung teaches a method comprising isolating primary mammalian chondrocytes from femoral condyles by enzymatic disaggregation and culturing said chondrocytes on porous granules of hyaluronic acid for over a year (Example 1 at column 5 et seq., in particular column 6, line 53, through column 7, line 2). The medium of Cheung includes DMEM supplemented with horse serum and antibiotics (column 6, lines 60-61); Cheung makes no mention of any of the components recited in claims 11, 14, or 17 being present in their medium. Chondrocytes cultured using the method of Cheung express type II collagen, but not type I collagen (column 8, line 60, through column 9, line 24; and column 9, lines 66-68). Claim 21 is included in this rejection for that embodiment in which the predetermined number of passages is zero.

Cheung does not teach isolating chondrocytes from mandibular condyles. Cheung does not teach isolating cells from a neonatal mammal.

Bhalerao teaches incubating neonatal mouse mandibular condyles in DMEM/F-12 containing 0.1% collagenase, a protease, and agitating the tissue to liberate cells into the medium (page 370, column 2, under "Preparation of cell suspension"). The method of Bhalerao yields chondrocytes (ibid.).

A person of ordinary skill in the art would have had a reasonable expectation of success in substituting the mandibular condyles of neonatal mammals of Bhalerao for the femoral condyles of Cheung because Bhalerao teaches that mandibular condyles are a source of chondrocytes and because Cheung teaches that chondrocytes may be isolated from many different cartilages (column 6, lines 5-10). These teachings indicate that neonatal mandibular condyles and femoral condyles are functional equivalents in this art; therefore, substituting one for the other would have constituted routine optimization at the time of the invention. See *KSR International Co. v. Teleflex Inc.*, 82 USPQ2d 1385 (U.S. 2007).

It would therefore have been obvious to a person of ordinary skill in the art at the time the invention was made to substitute the neonatal mandibular condyles of Bhalerao for the femoral condyles of Cheung because the two are art-accepted equivalents in this application.

Therefore, the invention as a whole would have been *prima facie* obvious to a person of ordinary skill at the time the invention was made.

Applicant's comments regarding the rejections of record have been considered to the extent they read on this new ground of rejection, which was necessitated by the amendment to claim 1. Applicant alleges that Bhalerao's method does not yield an

enhanced population chondrocytes (Reply, page 21, last paragraph, and page 26, paragraph 4). These arguments have been fully considered, but they are not persuasive for the reasons set forth above in the rejection under 35 U.S.C. § 102. It is noted for the record that this rejection does not include any claims in which the cells are required to grow in a monolayer.

Claims 1-5, 11, 14, 17-23, and 108 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tubo et al. (1998, U.S. Patent 5,723,331; reference B) taken in view of Bhalerao (1995, *Tissue and Cell* 27: 369-382).

Tubo teaches a method comprising isolating chondrocytes from a source of cartilage by several rounds of enzymatic disaggregation (column 10, lines 27-47; column 11, lines 1-4; and column 17, line 66, through column 18, line 17). Tubo teaches expanding the resulting chondrocytes in monolayer culture, including passaging them up to about 7 to 10 times (column 11, line 54, through column 12, line 51; and column 18, lines 19-27). After the chondrocytes have been expanded, Tubo teaches placing them into a well with a cell-contacting, cell-abhesive surface that induces the chondrocytes to form aggregates that secrete type II collagen and sulfated proteoglycans, i.e. synthetic cartilage (column 13, line 60, through column 14, line 13; column 15, line 54, through column 16, line 13; and column 19, line 45, through column 20, line 30). The culturing of Tubo is carried out under standard tissue culture conditions for up to 90 days (37^{o}C, 5% CO_2; column 15, line 58, e.g.).

Tubo does not teach isolating chondrocytes from mandibular condyles. Tubo does not teach isolating cells from a neonatal mammal.

Bhalerao teaches incubating neonatal mouse mandibular condyles in DMEM/F-12 containing 0.1% collagenase, a protease, and agitating the tissue to liberate cells into the medium (page 370, column 2, under "Preparation of cell suspension"). The method of Bhalerao yields chondrocytes (ibid.).

A person of ordinary skill in the art would have had a reasonable expectation of success in substituting the mandibular condyles of neonatal mammals of Tubo for the articular cartilage of Tubo because Bhalerao teaches that mandibular condyles are a source of chondrocytes and because Tubo teaches that chondrocytes may be isolated from many different sources (column 11, lines 1-4, e.g.). These teachings indicate that neonatal mandibular condyles and articular cartilage are functional equivalents in this art; therefore, substituting one for the other would have constituted routine optimization at the time of the invention. See *KSR International Co. v. Teleflex Inc.*, 82 USPQ2d 1385 (U.S. 2007).

It would therefore have been obvious to a person of ordinary skill in the art at the time the invention was made to substitute the neonatal mandibular condyles of Bhalerao for the articular cartilage of Tubo because the two are art-accepted equivalents in this application.

Therefore, the invention as a whole would have been *prima facie* obvious to a person of ordinary skill at the time the invention was made.

Applicant's comments regarding the rejections of record have been considered to the extent they read on this new ground of rejection, which was necessitated by the amendment to claim 1. Applicant alleges that Bhalerao's method does not yield an enhanced population chondrocytes (Reply, page 21, last paragraph, and page 26, paragraph 4). These arguments have been fully considered, but they are not persuasive for the reasons set forth above in the rejection under 35 U.S.C. § 102. It is noted for the record that this rejection does not include any claims in which the cells are required to grow in a monolayer.

No claims are allowed.

Applicant is requested to specifically point out the support for any amendments made to the disclosure in response to this Office action, including the claims (MPEP 714.02 and 2163.06). In doing so, applicant is requested to refer to pages and line numbers in the as-filed specification, **not** the published application. Due to the procedure outlined in MPEP § 2163.06 for interpreting claims, it is noted that other art may be applicable under 35 U.S.C. § 102 or 35 U.S.C. § 103(a) once the aforementioned issue(s) is/are addressed.

Applicant is requested to provide a list of all copending U.S. applications that set forth similar subject matter to the present claims. A copy of such copending claims is requested in response to this Office action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lora E. Barnhart whose telephone number is 571-272-1928. The examiner can normally be reached on Monday-Thursday, 9:00am - 5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Lora E Barnhart/
Primary Examiner, Art Unit 1651